

hematology, which require particle analysis, and tests of chemistry/immunochemistry or serology, which require quantitative light analysis.

What is needed is a method and an apparatus for evaluating a sample of substantially undiluted biologic fluid, one capable of providing accurate results, one that does not use a significant volume of reagent(s), one that does not require sample fluid flow during evaluation, one that can perform particulate component and chemical component analyses, and one that is cost-effective.

#### DISCLOSURE OF THE INVENTION

It is, therefore, an object of the present invention to provide an apparatus for analyzing biologic fluid samples that has the capacity to provide analytical data for a variety of disciplines including, but not limited to, hematology, biologic chemistry, immunochemistry, serology, immunology, urinalysis, immunoassay, antibiotic sensitivity, and bacterial growth.

It is another object of the present invention to provide a single apparatus for analyzing biologic fluid samples that has the capacity to perform a greater number of tests than can be done on any single presently available device.

It is another object of the present invention to provide an apparatus for analyzing biologic fluid samples that uses a quiescent sample, and thereby avoids the problems associated with devices utilizing fluid flow, particularly those utilizing fluid flow outside the sample chamber and those utilizing fluid flow during the analysis process.

It is another object of the present invention to provide an apparatus for analyzing biologic fluid samples that has the capacity to search a biologic fluid sample for an optimum region to perform a given test.

It is another object of the present invention to provide an apparatus for analyzing biologic fluid samples that has the capacity to determine the volume of a given sample field in a fluid sample chamber.

According to the present invention, an apparatus for analyzing a sample of biologic fluid quiescently residing within a chamber is provided. The apparatus includes a light source, a positioner, a means for determining the volume of a sample field, and an image dissector. The light source is operable to illuminate a sample field of known, or ascertainable, area. The positioner is operable to selectively change the position of one of the chamber or the light source relative to the other, thereby permitting selective illumination of all regions of the sample. The means for determining the volume of a sample field can determine the volume of a sample field illuminated by the light source. The image dissector is operable to convert an image of light passing through or emanating from the sample field into an electronic data format.

An advantage of the present invention is that the present invention apparatus for analyzing a sample of biologic fluid is substantially more versatile than any presently available apparatus capable of analyzing biologic fluid. For example, the present invention has utility in numerous fields including, but not limited to, hematology, biologic chemistry, immunochemistry, serology, immunology, urinalysis, immunoassays, antibiotic sensitivity, and bacterial growth. From an equipment standpoint, this versatility will give many medical offices and laboratories analytical capability that was realistically unavailable heretofore because of cost, space, manpower, training, etc. When testing a blood sample for anemia, for example, it is common to analyze the sample using hematological tests such as hemoglobin, hematocrit, and reticulocyte count, and also to analyze the sample using chemical tests to establish the presence and quantity of iron or ferritin and immunochemical tests such as B-12 and folate. Using presently available devices, the medical office or laboratory would typically rely on an impedance counter or flow system to determine the hematological parameters and a chemical analyzer or immunochemistry system to determine the other analytical parameters, any of which may not be readily available to the office or laboratory. The present invention apparatus, in contrast, can perform all of these tests. For those medical offices and

laboratories that presently do have multiple discipline analysis capability, the present invention will substantially reduce equipment cost, space required, manpower and training.

The present invention can also, in most instances, increase the number of tests possible on one analysis device in a particular field. In the field of hematology, for example, the present invention can be programmed to perform analyses such as hematocrit and hemoglobin evaluation, white blood cell count, platelet count, red blood cell indices, red blood cell morphology, five-part differential, reticulocytes evaluation, white blood cell subset analyses, sedimentation rate (ESR), and sepsis detection. As far as is known, no single presently available analysis device can perform all of these analyses.

Another advantage of the present invention apparatus for analyzing a biologic sample is that it does not require substantial dilution or complex fluid handling apparatus. As stated in the Background of the Invention, analyzing whole blood in an impedance or optical flow cytometer has several drawbacks relating to the amount the sample must be diluted and the internal plumbing of the device. The present invention apparatus, on the other hand, requires relatively little or no dilution of the biologic sample, has no internal plumbing, and does not require external calibration. A person of skill in the art will recognize that it is a significant advantage to provide an apparatus with increased reliability. Specifically, the present invention's lack of plumbing eliminates the possibility of downtime attributable to plumbing leaks or that due to a sensor being miscalibrated. The present invention also avoids the expensive service contracts associated with many flow cytometers. Perhaps most importantly, the lack of need for any external calibration removes a large source of potential errors and considerable operational complexity.

Another advantage of the present invention apparatus for analyzing a biologic sample is that it provides faster results for a complete set of tests. In many cases, faster test results mean better patient care because a patient may be evaluated with the results of the tests in hand, rather than the current practice of releasing the patient and requiring a repeat visit if unusual results are encountered. Faster test results also enable the medical office or laboratory